Contents

Volume 58, Number 1, July 2004

Editors' view

1 What is a clinical trial?: *J.K. Aronson*

Pharmacokinetics

4 Food does not affect the pharmacokinetics of solifenacin, a new muscarinic receptor antagonist: results of a randomized crossover trial: *T. Uchida, W.J. Krauwinkel, H. Mulder & R.A. Smulders*

8 Quantitative justification for target concentration intervention – parameter variability and predictive performance using population pharmacokinetic models for aminoglycosides: *I. Matthews, C. Kirkpatrick & N. Holford*

20 Pharmacokinetics of fosfluconazole and fluconazole following multiple intravenous administration of fosfluconazole in healthy male volunteers: *S. Sobue, K. Tan, G. Layton, M. Eve & J.B. Sanderson*

Pharmacodynamics

26 Effects of hydrofluoroalkane formulations of ciclesonide 400 µg once daily *vs* fluticasone 250 µg twice daily on methacholine hyper-responsiveness in mild-to-moderate persistent asthma: *D.K.C. Lee, K. Haggart, G.P. Currie, C.E. Bates & B.J. Lipworth*

34 Single and short-term dosing effects of levocetirizine on adenosine monophosphate bronchoprovocation in atopic asthma: *D.K.C. Lee, R.D. Gray, A.M. Wilson, F.M. Robb, P.C. Soutar & B.J. Lipworth*

Pharmacokinetics/pharmacodynamics

40 Pharmacokinetics and pharmacodynamics of terbogrel, a combined thromboxane A_2 receptor and synthase inhibitor, in healthy subjects: *B.D. Guth, H. Narjes, H.-D. Schubert, P. Tanswell, A. Riedel & G. Nehmiz*

Drug interactions

52 Effects of tetracycline on the pharmacokinetics of halofantrine in healthy volunteers: *P.U. Bassi, C.O. Onyeji & O.E. Ukponmwan*

56 Effects of regular consumption of grapefruit juice on the pharmacokinetics of simvastatin: *J.J. Lilja, M. Neuvonen & P.J. Neuvonen*

Clinical trials

61 Determining the reporting quality of RCTs in clinical pharmacology: *E. Mills, Y.K. Loke, P. Wu, V.M. Montori, D. Perri, D. Moher & G. Guyatt*

Pharmacogenetics

66 Thiopurine S-methyltransferase genetic polymorphism in the Thai population: *S. Srimartpirom, W. Tassaneeyakul, V. Kukongviriyapan & W. Tassaneeyakul*

Adverse drug reactions

71 Acute and clinically relevant drug-induced liver injury: a population based case-control study: *F.J. de Abajo, D. Montero, M. Madurga & L.A.G. Rodríguez*

Drug safety

81 Comparative cardiac safety of low-dose thioridazine and low-dose haloperidol: *S. Hennessy, W.B. Bilker, J.S. Knauss, S.E. Kimmel, D.J. Margolis, M.F. Morrison, R.F. Reynolds, D.B. Glasser & B.L. Strom*

Clinical toxicology

88 Alprazolam is relatively more toxic than other benzodiazepines in overdose: *G.K. Isbister, L. O'Regan, D. Sibbritt & I.M. Whyte*

Short report

96 Iohexol contrast medium induces QT prolongation in amiodarone patients: *M. Goernig, T. Kirmeier, A. Krack, C.S. Hartog, H.R. Figulla & U. Leder*

Book Review

99 Clarke's Analysis of Drugs and Poisons, 3rd Edition: *edited by A.C. Moffatt, M.D. Osselton & B. Widdop; reviewed by M. Lennard*

Letter to the editors

100 Reboxetine may be helpful in the treatment of amphetamine withdrawal: *D. Cox, R. Bowers & A. McBride*

102 Errata

103 Proceedings of the Dutch Society for Clinical Pharmacology and Biopharmacy, 3 October 2003

Volume 58, Number 2, August 2004

Editors' view

117 Littluns and biguns: *J.K. Aronson*

Review

119 What is the best size descriptor to use for pharmacokinetic studies in the obese?: *B. Green & S.B. Duffull*

Pharmacodynamics

134 A comparison of lung function methods for assessing dose–response effects of salbutamol: *C.M. Houghton, A.A. Woodcock & D. Singh*

Pharmacokinetics

142 Population pharmacokinetics of APOMINE™: A meta-analysis in cancer patients and healthy males: *P.L. Bonate, S. Floret & C. Bentzen*

156 Bioavailabilities of rectal and oral methadone in healthy subjects: *O. Dale, P. Sheffels & E.D. Kharasch*

Pharmacogenetics

163 Phenotyping and genotyping study of thiopurine S-methyltransferase in healthy Chinese children: A comparison of Han and Yao ethnic groups: *J.-P. Zhang, Y.-Y. Guan, J.-H. Wu, A.-L. Xu, S. Zhou & M. Huang*

169 Endothelial venodilator response in carriers of genetic polymorphisms involved in NO synthesis and degradation: *R. Fricker, C. Hesse, J. Weiss, Y. Tayrouz, M.M. Hoffmann, K. Unnebrink, U. Mansmann & W.E. Haefeli*

Pharmacoepidemiology

178 Antipsychotic polypharmacy in patients with schizophrenia: a multicentre comparative study in East Asia: *K. Sim, A. Su, S. Fujii, S.-Y. Yang, M.-Y. Chong, G.S. Ungvari, T. Si, E.K. Chung, H.-Y. Tsang, Y.H. Chan, S. Heckers, N. Shinfuku & C.H. Tan*

184 Increased treatment failure after 3-days' courses of nitrofurantoin and trimethoprim for urinary tract infections in women: a population-based retrospective cohort study using the PHARMO database: *W.G. Goettsch, R. Janknegt & R.M.C. Herings*

Drug disposition

190 Robustness of chlorzoxazone as an *in vivo* measure of cytochrome P450 2E1 activity: *L. Ernstgård, M. Warholm & G. Johanson*

Therapeutics

201 Leflunomide in active rheumatoid arthritis: a prospective study in daily practice: *E.N. van Roon, T.L.T.A. Jansen, L. Mourad, P.M. Houtman, G.A.W. Bruyn, E.N. Griep, B. Wilffert, H. Tobi & J.R.B.J. Brouwers*

Short reports

209 *In vitro* fertilization and childhood retinoblastoma: *B.D. Bradbury & H. Jick*

212 *In vitro* blood distribution and plasma protein binding of the tyrosine kinase inhibitor imatinib and its active metabolite, CGP74588, in rat, mouse, dog, monkey, healthy humans and patients with acute lymphatic leukaemia: *O. Kretz, H.M. Weiss, M.M. Schumacher & G. Gross*

217 Training in paediatric clinical pharmacology in the UK: *I. Choonara, O. Dewit, E. Harrop, S. Howarth, P. Helms, D. Kanabar, W. Lenney, G. Rylance & P. Vallance*

219 Plasma concentrations during naltrexone implant treatment of opiate-dependent patients: *L. Olsen, A.S. Christophersen, G. Frogopsahl, H. Waal & J. Mørland*

Letters

223 Acute hypotensive effects of oral cisapride and erythromycin in healthy subjects: *A.A. Mangoni, J.C.T. Close, S. Rodriguez, R.A. Sherwood, C.A. Bryant, C.G. Swift & S.H.D. Jackson*

225 The use of urine to clarify the genotype of a patient with toxic phenytoin concentrations who had undergone peripheral blood stem cell transplantation: *N. Ariyoshi, K. Sho-no, M. Nishimura, M. Ito, H. Nakamura, T. Asai, Y. Saitoh, T. Ishizaki & M. Kitada*

Book review

227 Stephens' Detection of New Adverse Drug Reactions, 5th edn: *edited by J. Talbot & P. Waller; reviewed by J. Aronson*

228 Erratum

Announcements

229 Notice of forthcoming events

Volume 58, Number 3, September 2004

Editors' view

231 Over-the-counter medicines: *J.K. Aronson*

Pharmacodynamics

235 Can coadministration of oxycodone and morphine produce analgesic synergy in humans? An experimental cold pain study: *M. Grach, W. Massalha, D. Pud, R. Adler & E. Eisenberg*

243 Alpha-lipoic acid does not acutely affect resistance and conduit artery function or oxidative stress in healthy men: *J.E. Sharman, P. Gunaruwan, W.L. Knez, M. Schmitt, S.A. Marsh, G.R. Wilson, J.R. Cockcroft & J.S. Coombes*

Pharmacokinetics

249 Intravenous indometacin in preterm infants with symptomatic patent ductus arteriosus. A population pharmacokinetic study: *J.M. Smyth, P.S. Collier, M. Darwish, J.S. Millership, H.L. Halliday, S. Petersen & J.C. McElnay*

259 Vancomycin pharmacokinetics in critically ill patients receiving continuous venovenous haemodiafiltration: *M.E. DelDot, J. Lipman & S.E. Tett*

269 A comparison of the bioequivalence of two formulations of epoetin alfa after subcutaneous injection: *A. Togawa, T. Tanaka, S. Nagashima, H. Keta, Y. Kobayashi, Y. Nishikawa, M. Yanai & H. Tanaka*

Drug metabolism

277 Characterization of human cytochrome P450 enzymes catalyzing domperidone N-dealkylation and hydroxylation *in vitro*: *B.A. Ward, A. Morocho, A. Kandil, R.E. Galinsky, D.A. Flockhart & Z. Desta*

288 A convenient five-drug cocktail for the assessment of major drug metabolizing enzymes: a pilot study: *A. Sharma, S. Pilote, P.M. Bélanger, M. Arsenault & B.A. Hamelin*

Pharmacoepidemiology

298 First-trimester exposure to amoxycillin/clavulanic acid: a prospective, controlled study: *M. Berkovitch, O. Diav-Citrin, R. Greenberg, M. Cohen, M. Bulkowstein, S. Shechtman, O. Bortnik, J. Arnon & A. Ornoy*

303 Statins and newly diagnosed diabetes: *S.S. Jick & B.D. Bradbury*

310 Recent trends in (under)treatment of hypercholesterolaemia in the Netherlands: *A.K. Mantel-Teeuwisse, W.M.M. Verschuren, O.H. Klungel, A. de Boer & D. Kromhout*

Drug regulation

317 Venetian treacle and the foundation of medicines regulation: *J.P. Griffin*

Short reports

326 Is decreased libido associated with the use of HMG-CoA-reductase inhibitors?: *L. de Graaf, A.H.P.M. Brouwers & W.L. Diemont*

329 Severe overdosage with the antiepileptic drug oxcarbazepine: *J.M. van Opstal, R. Janknegt, J. Cilissen, W.H.V.M. L'Ortije, J.E. Nel & F. De Heer*

332 Genetic polymorphism of cytochrome P450 2C19 in healthy Malaysian subjects: *Y.S. Yang, L.P. Wong, T.C. Lee, A.M. Mustafa, Z. Mohamed & C.C. Lang*

Book reviews

336 Drug Delivery Systems in Cancer Therapy: *edited by D.M. Brown; reviewed by L.D. Lewis*

337 Modern Pharmacology with Clinical Applications, 6th edn: *edited by C.R. Craig & R.E. Stitzel; reviewed by J. Mucklow*

Letters to the editor

338 Trimethoprim-induced hyperkalaemia – lessons in data mining: *M. Hauben*

340 The conclusion that 'ultramolecular homeopathy has no observable clinical effects' is not supported by the data: *E. Shalts & S. Shiflett*

Volume 58, Number 4, October 2004

Editors' view

343 Classifying drug interactions: *J.K. Aronson*

Pharmacokinetics

345 Comparison of the pharmacokinetics of miconazole after administration via a bioadhesive slow release tablet and an oral gel to healthy male and female subjects: *J.-M. Cardot, C. Chaumont, C. Dubray, D. Costantini & J.-M. Aiache*

352 Pharmacokinetics and renal excretion of desmopressin after intravenous administration to healthy subjects and renally impaired patients: *H. Agersø, L.S. Larsen, A. Riis, U. Lövgren, M.O. Karlsson & T. Senderovitz*

Pharmacodynamics

359 Comparison of bronchoprotective and bronchodilator effects of a single dose of formoterol delivered by hydrofluoroalkane and chlorofluorocarbon aerosols and dry powder in a double blind, placebo-controlled, crossover study: *C.M. Houghton, S.J. Langley, S.D. Singh, J. Holden, A.P.M. Preti, D. Acerbi, G. Poli & A. Woodcock*

Pharmacokinetics/Pharmacodynamics

367 Models for time-varying covariates in population pharmacokinetic-pharmacodynamic analysis: *U. Wählby, A.H. Thomson, P.A. Milligan & M.O. Karlsson*

378 Pharmacokinetic/pharmacodynamic models for the depletion of Vβ5.2/5.3 T cells by the monoclonal antibody ATM-027 in patients with multiple sclerosis, as measured by FACS: *P.-H. Zingmark, C. Edenius & M.O. Karlsson*

Drug interactions

390 Lack of effect of bezafibrate and fenofibrate on the pharmacokinetics and pharmacodynamics of repaglinide: *L.I. Kajosaari, J.T. Backman, M. Neuvonen, J. Laitila & P.J. Neuvonen*

397 Effect of ketoconazole on the pharmacokinetics of rosiglitazone in healthy subjects: *J.-Y. Park, K.-A. Kim, J.-G. Shin & K.Y. Lee*

403 Drug interaction between St John's wort and quazepam: *A. Kawaguchi, M. Ohmori, S. Tsuruoka, K. Nishiki, K. Harada, I. Miyamori, R. Yano, T. Nakamura, M. Masada, & A. Fujimura*

Drug safety

411 Cumulative high doses of inhaled formoterol have less systemic effects in asthmatic children 6–11 years-old than cumulative high doses of inhaled terbutaline: *R. Kaae, L. Agertoft, S. Pedersen, S.L. Nordvall, C. Pedroletti, T. Bengtsson, I. Johannes-Hellberg & J. Rosenborg*

Pharmacoepidemiology

419 European Surveillance of Antimicrobial Consumption (ESAC): Data Collection Performance and Methodological Approach: *R.H. Vander Stichele, M.M. Elseviers, M. Ferech, S. Blot, H. Goossens & the ESAC Project Group*

Short reports

429 Pharmacokinetics of oral fumarates in healthy subjects: *N.H.R. Litjens, J. Burggraaf, E. van Strijen, C. van Gulpen, H. Mattie, R.C. Schoemaker, J.T. van Dissel, H.B. Thio & P.H. Nibbering*

433 Effect of the oral renin inhibitor aliskiren on the pharmacokinetics and pharmacodynamics of a single dose of warfarin in healthy subjects: *W. Dieterle, S. Corynen & J. Mann*

437 Undeclared exposure to St. John's wort in hospitalized patients: *M. Martin-Facklam, K. Rieger, K.-D. Riedel, J. Burhenne, I. Walter-Sack & W.E. Haefeli*

Book review

442 Anticoagulants, antiplatelets and thrombolytics: *edited by S.A. Mousa; reviewed by R.F. Storey*

Letters to the editor

443 Association of the *CYP3A5* A6986G (*CYP3A5*3*) polymorphism with saquinavir pharmacokinetics: *M. Fröhlich, M.M. Hoffmann, J. Burhenne, G. Mikus, J. Weiss & W.E. Haefeli*

445 Ritodrine-induced transient neutropenia in newborn twins after *in utero* exposure: Report of first cases: *N. Okumus, C. Türkyilmaz, E.E. Önal, Y. Atalay, E. Koç & T. Nas*

447 Intranasal and inhaled corticosteroids in allergic rhinitis and asthma: *D.K.C. Lee & B.J. Lipworth*

Volume 58, Number 5, November 2004

Editors' view

449 *Professor E.J. Begg*

Reviews

452 Drug development and use in the elderly: search for the right dose and dosing regimen: *R.R. Shah*

Pharmacodynamics

470 Effect of oral linezolid on the pressor response to intravenous tyramine: *M.V. Cantarini, C.J. Painter, E.M. Gilmore, C. Bolger, C.L. Watkins & A.M. Hughes*

Pharmacokinetics/pharmacodynamics

476 Effect of itraconazole on the pharmacokinetics and pharmacodynamics of a single oral dose of brotizolam: *T. Osanai, T. Ohkubo, N. Yasui, T. Kondo & S. Kaneko*

Pharmacogenetics

482 Internet based clinical trial protocols – as applied to a study of warfarin pharmacogenetics: *J.D. Lindh, M. Kublickas, M. Westgren & A. Rane*

Drug distribution

488 Adsorption of oxacalcitriol by polysulphone haemodialyser in patients with secondary hyperparathyroidism: *S. Tsuruoka, H. Yamamoto, T. Ioka, H. Ando, T. Saito & A. Fujimura*

Therapeutics

496 Influence of socioeconomic status on the quality of prescribing in the elderly – a population based study: *E. Odubanjo, K. Bennett & J. Feely*

503 Evaluation of the clinical value of pharmacists' modifications of prescription errors: *H. Buurma, P.A.G.M. De Smet, H.G.M. Leufkens & A.C.G. Egberts*

512 Clinical and functional responses to salbutamol inhaled via different devices in asthmatic patients with induced bronchoconstriction: *F. Lavorini, P. Geri, M. Luperini, N.M. Maluccio, L. Mariani, C. Marmai, M. Pistolesi & G.A. Fontana*

521 Comparison of gentamicin dose estimates derived from manual calculations, the Australian 'Therapeutic Guidelines: Antibiotic' nomogram and the SeBA-GEN and DoseCalc software programs: *M. Mohan, K.T. Batty, J.A. Cooper, R.E. Wojnar-Horton & K.F. Ilett*

528 Association between adherence to statin therapy and lipid control in Hong Kong Chinese patients at high risk of coronary heart disease: *C.W.R. Cheng, K.-S. Woo, J.C.N. Chan, B. Tomlinson & J.H.S. You*

536 Comparison of tincture of opium and methadone to control opioid withdrawal in a Thai treatment centre: *J. Jittiwutikarn, R. Ali, J.M. White, F. Bochner, A.A. Somogyi & D.J.R. Foster*

542 A randomized, double-blind, placebo controlled trial of melatonin add-on therapy in epileptic children on valproate monotherapy: effect on glutathione peroxidase and glutathione reductase enzymes: *M. Gupta, Y.K. Gupta, S. Agarwal, S. Aneja & K. Kohli*

Short reports

548 *MDR1* haplotypes derived from exons 21 and 26 do not affect the steady-state pharmacokinetics of tacrolimus in renal transplant patients: *I. Mai, E.S. Perloff, S. Bauer, M. Goldammer, A. Johne, G. Filler, K. Budde & I. Roots*

554 Tolerability of spironolactone in patients with chronic heart failure – a cautionary message: *M.D. Witham, N.D. Gillespie & A.D. Struthers*

Letters to the editors

558 'Ally McBeal heart?' – Drug induced cardiomyopathy in a young woman: *A.M. Crean & J.E.F. Pohl*

560 Drug-induced pancreatitis: lessons in data mining: *M. Hauben & L. Reich*

563 Errata

Volume 58, Number 6, December 2004

Editors' view

569 Medicines regulation and clinical pharmacology: *N.S. Baber, J.M. Ritter & J.K. Aronson*

Reviews

571 The changing scene of the regulation of medicines in the UK. Paper from The Use of Medicines: Regulation & Clinical Pharmacology in the 21st Century Symposium – December 2003: *A. Breckenridge*

575 NICE and the public health: *M.D. Rawlins*

581 Risk : benefit assessment of old medicines: *S. Garattini & V. Bertelé*

587 Current approaches to prevent NSAID-induced gastropathy – COX selectivity and beyond: *J.C. Becker, W. Domschke & T. Pohle*

601 The use of pharmacokinetic and pharmacodynamic data in the assessment of drug safety in early drug development: *D.K. Walker*

Pharmacokinetics/pharmacodynamics

609 Subjective and physiological responses among racemic-methadone maintenance patients in relation to relative (S)- *vs.* (R)-methadone exposure: *T.B. Mitchell, K.R. Dyer, D. Newcombe, A. Salter, A.A. Somogyi, F. Bochner & J.M. White*

618 A semimechanistic and mechanistic population PK–PD model for biomarker response to ibandronate, a new bisphosphonate for the treatment of osteoporosis: *G. Pillai, R. Gieschke, T. Goggin, P. Jacqmin, R.C. Schimmer & J.-L. Steimer*

Drug interactions

632 Effect of efavirenz treatment on the pharmacokinetics of nelfinavir boosted by ritonavir in healthy volunteers: *C.J.L. la Porte, M.J.A. de Graaff-Teulen, E.P.H. Colbers, D.S. Voncken, S.M. Ibanez, P.P. Koopmans, Y.A. Hekster & D.M. Burger*

641 Influence of ketoconazole on azimilide pharmacokinetics in healthy subjects: *M.E. Mouelhi, D.J. Worley, B. Kuzmak, A.J. Destefano & G.A. Thompson*

Pharmacoepidemiology

648 Medication reviews in the community: results of a randomized, controlled effectiveness trial: *L. Sorensen, J.A. Stokes, D.M. Purdie, M. Woodward, R. Elliott & M.S. Roberts*

Therapeutics

665 Prescribing for osteoporosis following the use of inhaled and oral glucocorticoids in general practice: *D. Williams, K. Bennett & J. Feely*

Short reports

673 Serotonin reuptake inhibitor induced sensory disturbances: *S.K. Praharaj*

Letters to the editors

675 A case report of rhabdomyolysis with pentamidine that prompted a retrospective evaluation of a pharmacovigilance tool under investigation: *M. Hauben & L. Reich*

677 Multi-dosage vials, potential for overdose: *A. Kambal, M. Najem & T.S. Hussain*

678 Hypogeusia as an adverse reaction of phenytoin: *C.R. Baumann, P.M. Ott & A.M. Siegel*

680 Errata

681 Proceedings from the 15th Annual symposium of the London Hypertension Society, 25th May 2004

689 Indices for Volume 58

696 Reviewers for 2004